Medical Device Manufacturers

Presentation to the U.S. Federal Trade Commission

September 10, 2002



GPOs – IS THERE A PROBLEM

- Senate Judiciary
- Federal Trade Commission
- HHS Office of Inspector General
- The New York Times
- Industry Trade Associations
- MX Magazine
- Modern Healthcare
- The Gray Sheet
- Anti-Trust Experts
- GPOs Themselves



Exclusionary Agreements

- Sole Source Agreements While the GPO contracts do not require 100% compliance requirements, the 90% - 95% compliance in the contracts have the same exclusive dealing consequences
- <u>Bundling</u> GPOs give rebates and discounts on <u>unrelated</u> products from different manufacturers if the hospital commits to a high percentage of each product from the corresponding manufacturers on the menu
- Exclusionary Pricing- Non-Linear Market Share Based Pricing Schemes
- Vendor Fees These fees have distorted GPO's mission and loyalty to hospitals and patients
- Price Control Some GPOs have agreed to let rival manufacturers in on the condition that the rival offer their products at prices that are dramatically higher than being charged by the incumbent device maker



Masimo: Our GPO Experience

- Sole-source: GPO Hospital Members can only buy Tyco-Nellcor and are penalized for not reaching 90-95% compliance levels.
- <u>Exclusionary pricing</u>: Exponential price discounts are based on reaching 90-95% compliance levels.
- Bundling: Even if we gave the Masimo SET products away, hospitals still lose money for using Masimo SET products.
 - □ Purchasing Masimo can cost a hospital \$500K to \$1 million.
 - □ Significant discounts/rebates are tied to a group of unrelated products and can only be earned if <u>all</u> products in the bundle are purchased at 90-95% level.



Masimo Has 100% Success Rate in Free Markets

Sol	le-Source	GPOs
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Free Markets

	Premier	Novation	Consorta	AmeriNet	Independent Hospitals
Lost Deals	22	24	2	0	0
Hospital-Wide Conversion to Masimo	0%	10%	0%	60%	44%

Source: 2001 Masimo Sales Statistics



Masimo Bids 31% Less than Nellcor for Novation Contract and Loses

	Pulse Oximeter	Adult Reusable Sensor	Adult/Ped Adhesive Sensor	Infant Adhesive Sensor
Tyco-Nellcor	\$2,610	\$75	\$216	\$280
Masimo	\$1,580	\$75	\$139	\$192*

Masimo's Price is 31% Lower!**

^{*} Adjusted to reflect 2X life of LNOP durable sensor vs Nellcor Single use disposable sensors.

^{**} Weighted to reflect 80% of total dollar volume from disposable sensors.

Note: Using the worst contract pricing for each, resulted in Masimo pricing being approximately 46% less.



Bundling Schemes – Novation's Opportunity Spectrum Program

- Bundle includes 12 unrelated product categories from five vendors.
- Hospital earns rebates only if <u>all</u> 12 unrelated products in bundle are purchased at >95% compliance level.
- If a hospital ever becomes non-compliant, it not only loses over \$500K a year, but must return all rebates (~\$2M) received since entrance to the program.
- Hospitals forbidden from evaluating any competitive products.



Gibbons Surgical Novation's Opportunity Spectrum Program

- Trocar Access device for minimally invasive surgical procedures
- Gibbons on Contract Not within the "Opportunity Program" Bundle
- Gibbons Surgical product can produce 40-70 percent savings over J&J product
- Unrelated Products Bundled Surgical Gloves, Urology Products,
- Hospital earns rebates only if <u>all</u> 12 unrelated products in bundle are purchased at >95% compliance level.
- If a hospital ever becomes non-compliant, it not only loses current rebate, but must return all rebates received since entrance to the program.
- Results
 - □ 10 Years ago a multitude of Trocar Manufacturers Today approx. 10
 - Premier and Novation now contract with only 2 with Ethicon (J&J) being Opportunity Spectrum Vendor
 - Once hooked, a member hospital can't afford to deviate.



Impact of Anti-Competitive Conduct

- Decreases quality of products.
- Increases market power.
- Restrains market entry.
- Increases healthcare costs.
- Prevents new entrants from reaching economies of scale.
- Reduces investment capital available for medical device innovation and development.



Retractable's Experience With GPOs

Baptist Health System in San Antonio, Texas, reported that if it purchased even one box of VanishPoint® product, it would lose \$300,000 in rebates and incentives from Novation.

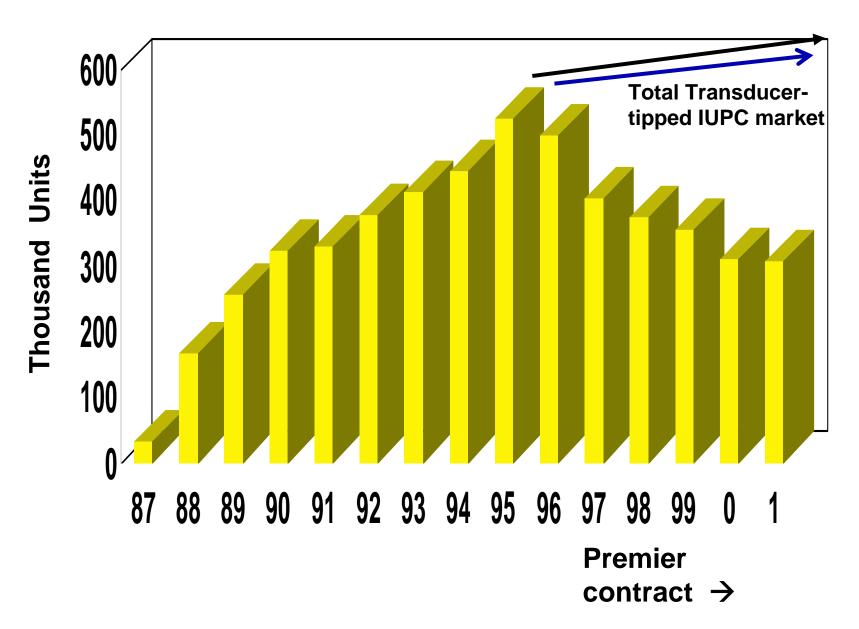


Utah Medical: Our Experience

- Because of physician confidence in Intran, Softrans did not become a factor in the marketplace until after Premier entered into an "exclusive" supply agreement with GCC in 1997
- UTMD contacted Premier and was told by Premier that IUPC's were too specialized and too small in sales dollars to be considered for a contract.
- Premier contracted for unrelated products with Tyco-Graphic Controls in mid 1997



Intran Annual U.S. Unit Sales





Utah Medical: Our Experience

- Premier encouraged Tyco-Graphic Controls to add other products in order to reduce its administrative contracting burden.
- No bidding process or clinical evaluation was undertaken by Premier regarding the important IUP surveillance tool, even though Premier had previously assured UTMD, because of Intran's widespread use by its hospitals, that Premier would request an UTMD bid if it decided to add specialty IUPC's to its list of contracted items.



Anticompetitive Effects

- Clinicians are denied access to the best medical products available causing patients to receive substandard care and increasing overall healthcare costs
- Breakthrough and evolutionary advances to products which compete with incumbent vendors' products can not compete on their own merits
- The government's own GAO study questioned whether GPOs are working toward their original mission of saving money
- Economies of scale, that are necessary to bring down price of product, are failing to be realized
- The future of medical device innovation is in jeopardy since VC funding is contingent upon GPO contracts



The Real Problem

- GPOs have become gatekeepers who sell and manage access to their members.
- Vendors purchase restricted access/exclusion through fees to the GPOs.
- Vendors rely on the purchased protection to gain/maintain share.
 - ☐ Little need for product innovation.
 - □ Little/no price pressure.



Specific Areas to Examine

- Problems occur most often with a large market share (>60%) product offered to a GPO by a significant vendor.
 - □ Pulse oximetry Tyco-Nellcor >90%
 - □ Syringes Beckton Dickinson >90%
 - □ Sutures Johnson & Johnson >90%
- Vendors willing to pay higher fees to restrict competition.
- Must look at specific product cases to uncover real problems.



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